

REMARKS

The foregoing amendment amends claims 1 and 35. Claims 1-40, 56 and 57, of which claims 1, 19 and 56 are independent, are now pending in the application. The following comments address all stated grounds for rejection and place the presently pending claims, as identified above, in condition for allowance.

Claim 1 is amended to change “tubular cartridge” to ---tubular cartridge insert--- in the last line of the claim.

Claim 35 is amended for purposes of clarity only. *No new matter is added.*

Claim Rejections Under 35 USC § 112

Claim 35 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants have amended the claims to specify that the first passage of the first leg and the second passage of the second leg are configured to be placed in fluid communication with the organs, which are not part of the claimed invention, and request that the rejection be reconsidered and withdrawn.

Claim Rejections Under 35 USC § 102

Applicants thank the Examiner for the close review of the claim and for indicating that claims 22, 27, 28 and 37 recite patentable subject matter. Claims 1-4, 6-9, 11, 13-21, 23-26, 30-32, 34, 36 and 38-40 are rejected under 35 U.S.C. § 102(e) as being anticipated by Kawamura (6,524,273). Applicants respectfully traverse the rejection and submit that claims 1-4, 6-9, 11, 13-21, 23-26, 30-32, 34, 36 and 38-40 distinguish patentably over the cited Kawamura reference. The Kawamura reference does not disclose a body fluid cartridge exchange platform device having openings configured to facilitate bi-directional insertion and removal of a tubular cartridge insert, *regardless* of which opening the tubular cartridge insert was installed through, as recited in independent claim 1, nor a bi-directionally insertable and removable cartridge, as set forth in claim 19. The Kawamura reference also fails to disclose a tubular cartridge insert that *sealably engages* inside the platform housing of a platform device, as also recited in claims 1 and 19.

Various embodiments of the present invention provide a body fluid cartridge exchange platform device having a hollow tubular platform housing. As recited in claim 1, the hollow tubular platform housing has a first end with a first opening and a second end with a second opening, wherein the first opening and the second opening facilitate insertion of a tubular cartridge insert that sealably engages inside the platform housing. Claim 1 further recites that the first opening and the second opening facilitate bi-directional installation and bi-directional removal of the tubular cartridge insert.

Applicants' specification describes the term bi-directional. By way of example, page 19, lines 24-32, provides:

In accordance with one embodiment of the present invention, the body fluid cartridge exchange platform device includes a tubular housing with an interior sealing surface having two openings, one at each end. The existence of the two horizontally oriented tubular openings enables a patient, family member, or healthcare worker, to bi-directionally insert, exchange and or remove the tubular cartridge inserts. The tubular and generally oval shaped cartridge inserts can be constructed of one or more assembled elements or parts to form one leak-proof tubular cartridge unit, or formed as a multi-cartridge, leak-proof assembly unit. The cartridge insert can easily be inserted, displaced, and removed out through either open end of the cartridge platform housing.... Further examples of the term "bi-directional" can be found throughout the specification, such as at page 15, lines 23-25, page 22, lines 19-20, page 38, lines 7-14, page 43, lines 29-31, and page 54, line 31 to page 55, line 2.

The Kawamura reference is directed to a needle-less blood access device for providing access to a blood vessel through the rotation of a columnar internal body 40 within an external body 20. According to the Examiner, through-holes 48 and 54 "facilitate bi-directional installation and removal of inserts regardless of which opening inserts are installed through". The Examiner further considers cannulas 68 and 70 to be inserts capable of such bi-directional installation and removal.

Applicants respectfully disagree. There is no teaching or suggestion in the Kawamura reference of the claimed body fluid cartridge exchange platform device that facilitates the recited bi-directional installation and removal of inserts. The cannulas 68 and 70 can only be inserted along a single direction through the top openings 46 and 52, respectively, of the through-holes 48 and 54, respectively, and removed along a single direction through the openings 46 and 52. Thus, the cannulas 68 and 70 must be removed from the same opening through which they are inserted. The cannulas 68 and 70 are incapable of being inserted or removed through the bottom openings 44 and 50, respectively, and can only be inserted or removed through the top openings 46 and 52 of the columnar internal body 40. In fact, the Kawamura reference teaches away from bi-directional installation and removal of inserts in a body fluid cartridge exchange platform device, because the disk 62 to which the cannulas 68 and 70 are connected prevents the cannulas 68 and 70 from passing through the through-holes and being removed via the bottom openings 44 and 50. In addition, the cannulas 68 and 70 are incapable of even being inserted through the bottom openings 44 and 50 into the through-holes, because the disk 62 limits the range of the cannulas and would prevent the cannulas from moving into a position so that insertion via the bottom openings would be possible. Therefore, the Kawamura does not teach or suggest the claimed bi-directional insertion and removal of an insert regardless of an opening through which an insert is installed.

In view of the above, Applicants submit that bi-directional installation and bi-directional removal involves an ability to install the cartridge insert in two directions and remove the cartridge insert in two directions. As Kawamura provides only a single direction for insertion of a cannula and a single, opposite direction for removal, Applicants submit that Kawamura does not teach or suggest the all the limitations of claim 1. Claims 2-7 and 13-15 are patentable at least by way of their dependency from claim 1.

In addition, the Kawamura reference does not teach or suggest a tubular cartridge insert that sealably engages inside the platform housing, as also recited in independent claims 1 and 19. The Examiner fails to address this recitation in the Office Action, and has therefore not met the requirements for establishing a *prima facie* case of anticipation. In addition, Applicants submit that, even if the cannulas can be considered bi-directional inserts, the Kawamura reference lacks

a teaching or suggestion that the cannulas “sealably engage” inside the columnar internal body 40.

For at least these reasons, Applicants submit that claims 1-4, 6-9, 11, 13-21, 23-26, 30-32, 34, 36 and 38-40 distinguish patentably over the Kawamura reference and request reconsideration and withdrawal of the rejection of the 35 U.S.C. § 102(e) rejection.

Claim Rejections Under 35 USC § 103

Regarding the rejection of claims 10, 33, 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawamura, as described above, the Kawamura reference does not teach or suggest the claimed bi-directional insertion and bi-directional removal of a cartridge insert from a housing, as recited in independent claims 1, 19 and 56, nor the sealing engagement of an insert with an interior of a housing, as also recited in independent claims 1, 19 and 56. Because independent claims 1 and 19 are patentable over the Kawamura reference, claim 10, which depends from claim 1, claim 33, which depends from independent claim 19 are also patentable. Independent claim 56 is also patentable for the same reasons outlined above.

Furthermore, Applicants respectfully disagree with the Examiner’s position that it would be obvious to use a common surgical tool as a cartridge insert tool for executing a bi-directional cartridge insert installation and removal, in particular because the Kawamura reference does not teach or suggest such bi-directional cartridge insert installation and removal. In addition, a common surgical tool would be incapable of executing the recited bi-directional cartridge insert installation and removal.

Regarding the rejection of claims 12 and 29 under 35 U.S.C. 103(a) as being unpatentable over Kawamura in view of Santerre et al. (5,798,115), because claims 1 and 19, from which claims 12 and 29 respectively depend, are patentable over the cited references, dependent claims 12 and 29 are patentable as well. Furthermore, Applicants also submit that motivation to combine the teachings of the Kawamura reference and the Santerre reference is lacking. The Examiner has not pointed to an object reason for combining the references, making the combination of the reference to make an obviousness-type rejection improper.

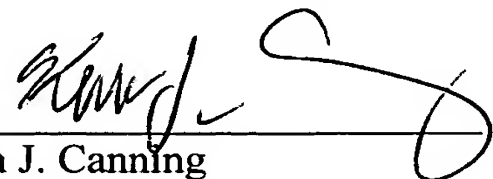
CONCLUSION

In view of the above amendment, applicants believe the pending application is in condition for allowance.

A petition for a one month extension of time is being filed concurrently herewith. Applicants believe no additional fee is due with this Amendment. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. ATA-333RCE from which the undersigned is authorized to draw.

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Respectfully submitted,

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